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RE: Serial No.09/854,802

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James V. Costigan, Reg. No. 25,669

February 5, 2007

Docket No.: 1259-001RECEIVED
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of)
Bojidar M. Stankov) Group Art: 1616
Examiner: Choi, Frank I.
Serial No.: 09/854,802)
Filed: May 14, 2001)

For: CONTROLLED RELEASE FORMULATIONS CONTAINING AN ACTIVE
INGREDIENT, PREFERABLY MELATONIN AND THE METHOD OF PREPARATION

New York, NY 10036
February 5, 2007

MS Appeal
Commissioner for Patents
P.O. BOX 1450
Alexandria, VA 22313-1450

REPLY BRIEF

The Examiner is urging that the portion of the specification that points out that since 95% of the melatonin was released "within the 5th hour" and not --within five hours--, the specification is not enabling. The specification is addressed to one of ordinary skill in the art of controlled release pharmaceuticals and it is well known that all measurements of controlled released products are based on a cumulative total of release active ingredient after a specified time. The language of the specification would have to require that release was "after the fourth hour and only during the fifth hour" in order to convey the meaning that the Examiner has ascribed to the present specification.

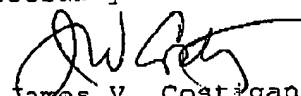
The specification at page 9, lines 24-29 described how the release test were carried out: "samples from the supernatant were taken out at predetermined times: 1, 5, 10, 30minutes and 1, 2, 3, 4, 5 and 6 hours" This information must be considered in connection with the reference to the fifth hour that the Examiner has cited. In the Lee et al., J. of Pharmaceutics 188 (1999) 71-80 citation which was cited by the

Examiner, a typical release curve appears which shows that the release vs. time is computed cumulatively and is not based on a release within any period of time within the middle of the test.

The Examiner's comments regarding the failure of the claims to recite "essential elements" fail to acknowledge that the reference to the "omitted elements" was a reference to "Stages" in the preparation of the claimed products. It is not necessary to recite processing information that is disclosed in a specification as an optimum method of making a particular product.

For these reasons, and the reasons set forth in the BRIEF, it is requested that the rejections of record be reversed.

Respectfully submitted,


James V. Costigan
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